IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Mark Shu et al.	Examiner:	Alvin J. Stewart
Serial No.:	10/792,186	Group Art Unit:	3738
Filed:	March 3, 2004	Docket:	M190.148.101 / P0011480.00
Due Date:	**February 16, 2008**		
Title:	SUTURE LOCKING ASSEMBLY AND METHOD OF USE		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

Applicant has filed a Notice of Appeal and requests review of the Final Rejection in the pending application. Please consider the following remarks during the Pre-Appeal Brief Conference.

Independent claims 1 and 51 are currently pending, as are claims 2-31 and 54-58 depending from claim 1, and claims 52 and 53 depending from claim 51. In the Final Office Action mailed November 16, 2007 ("FOA"), claims 1-11, 13-31, 51-55, 57, and 58 were rejected as being anticipated by Purdy et al., USPN 5,562,729 ("Purdy"). For the reasons below, Applicant respectfully contends that claim 1 is not anticipated by Purdy. In addition, many of the claims depending from claim 1 recite features that clearly define over Purdy, but have not been addressed by the Examiner in any way by the FOA (or the NFOA mailed June 4, 2007). The rejection of independent claim 51 is similarly devoid of any explanation. In sum, while the FOA (as well as the NFOA) provides an explanation of the rejection of claims 1, 5, 8, 9, and 11-13, the remaining claims are essentially unexamined and Applicant is unfairly prevented from providing a meaningful response. Withdrawal of the rejections and/or removal of the finality of the FOA is requested.

Independent Claim 1

Independent claim 1 relates to a suture locking assembly for use with a heart valve repair device, with the suture locking assembly comprising a rim and a suture band. The rim defines a first flange spaced from a second flange, with the suture band being maintained between the first and second flanges. Claim 1 recites that the suture locking assembly is configured to securely maintain a suture segment that is circumferentially pulled relative to at least one of the flanges

from a first position to a second position. The NFOA rejected claim 1 based on FIGS. 34-37 of Purdy, identifying stent ring 202 as the claimed "rim" and the suture (unnumbered in FIGS. 34-37, but identified in an attachment to the NFOA) used in mounting suture ring 176 to stent ring 202 as the claimed "suture band". Suture ring 176 was viewed as being the "suture segment" of claim 1, with pre-assembly of suture ring 176 to stent ring/rim 202 being the claimed "first position" and final assembly of suture ring 176 to stent ring/rim 202 via the suture as being the claimed "second position". The FOA appears to repeat this analysis, asserting that with respect to the "wherein" clause of claim 1, "the Examiner has to only look for a suture locking assembly that is capable of being pulled relative to at least one flange." *FOA, pg. 2.* It is respectfully submitted that this analysis is erroneous, and does not address features actually recited in claim 1.

In particular, claim 1 recites a structural configuration of the suture locking assembly relative to movement of a suture segment with respect to one of the flanges. In other words, the features of claim 1 are not directed toward a suture locking assembly that is "capable of being pulled" (as otherwise asserted by the FOA); rather, claim 1 is directed toward structural features of the suture locking assembly relative to a pulled suture segment that is apart from the suture locking assembly itself. A "pulling capability" of the alleged Purdy suture locking assembly is irrelevant to claim 1. Given this incorrect analysis in the FOA, the rejection of claim 1 should be withdrawn.

In addition, claim 1 recites that the suture locking assembly is configured to securely maintain a suture segment that is circumferentially pulled relative to at least one of the flanges from a first position to a second position. The purported suture locking assembly of Purdy does not teach a corresponding configuration. Rather, in the "first position" (i.e., pre-assembly) of Purdy, the "suture segment" (i.e., suture ring 176) cannot be securely maintained by the "suture band" (the unnumbered suture in FIG. 34). Conversely, in the "second position" (i.e., final assembly of Purdy), suture segment/suture ring 176 cannot be circumferentially pulled relative to stent ring/rim 202 (or the flanges 204). In other words, at no point of assembly of the suture/suture band of Purdy relative to stent ring/rim 202 can a suture segment be pulled circumferentially from a first position to a second position, and be securely maintained in the

second position. Thus, the structure of the "suture locking assembly" of Purdy does not anticipate the structural configuration of claim 1.

Claims Depending from Independent Claim 1

In a previous Response filed September 4, 2007 to the June 7, 2007 NFOA, Applicant specifically highlighted claims 4, 7, 10, 16, 20, 21, 26, 30, and 31 (all depending from claim 1) as reciting features not found in Purdy, and not addressed in the NFOA. The FOA fails to acknowledge or consider any of these deficiencies. The FOA further fails to provide a detailed explanation of the rejection of dependent claims 54, 55, 57, and 58. In short, the blanket rejection in the FOA of the claims highlighted below as somehow being anticipated by Purdy without an even cursory reference to Purdy of corresponding features dictates that the rejections be withdrawn; it is impossible for Applicant to address the rejections without at least some understanding of how the Examiner is interpreting Purdy as teaching each and every claimed feature. In the interest of brevity, distinguishing features of each of these claims are summarized below. Applicant respectfully submits that in the absence of any further explanation, Purdy cannot anticipate any of these claims.

Claim 4 recites that the rim defines a plurality of recesses. The FOA and NFOA fail to identify any corresponding features in FIGS. 34-37 of Purdy. At most, NFOA attachment appears to reference the single, annular gap between the flanges 204 as being a plurality of recesses. A single, continuous annular gap is not a plurality of recesses.

Claim 7 recites a plurality of segments, with each segment defining a recess. The FOA and NFOA fail to identify any corresponding features in FIGS. 34-37 of Purdy. A single, continuous annular gap is not a plurality of segments each defining a recess.

Claim 10 recites that the rim and the suture band are each a closed ring. The wound or wrapped suture of Purdy (unnumbered in FIGS. 34-37, but identified as the "suture band" in the NFOA attachment) is not a closed ring. The FOA and NFOA fail to provide any identification of a corresponding, closed ring suture band in Purdy.

Claim 16 recites that the suture locking assembly is configured to be positioned adjacent a sewing ring of the heart valve repair device. The FOA and NFOA fail to provide any

explanation of how Purdy anticipates these features. The purported "suture locking assembly" of Purdy is the sewing ring of the heart valve repair device. It is impossible for Purdy to teach a suture locking assembly positioned adjacent a separate sewing ring.

Claim 20 recites a plastic cover attached to the suture locking assembly opposite the rim. The FOA and NFOA fail to identify any corresponding features in Purdy.

Claim 21 recites that the suture band is formed of a metallic material. The FOA and NFOA fail to identify any corresponding features in Purdy. The purported suture band of Purdy (i.e., the suture used to mount the suture ring 176 to the stent ring/rim 202) is decidedly not formed of a metallic material.

Claim 26 recites that the rim and the suture band are each arcuately shaped. The FOA and NFOA fail to identify any corresponding features in Purdy. The purported suture band of Purdy (i.e., the suture used to mount the suture ring 176 to the stent ring/rim 202) is simply a flexible strand of thread, and thus cannot define a shape, let alone be "arcuately shaped".

Claim 30 recites that the suture band defines an engagement section including a connection body flanked by an outflow cut and an inflow cut. The FOA and the NFOA fail to identify any corresponding features in Purdy.

Claim 31 recites that the suture band defines at least one lateral stop rib. The FOA and NFOA fail to identify any corresponding features in of Purdy. The purported suture band of Purdy (i.e., the suture used to mount the suture ring 176 to the stent ring/rim 202) is simply a flexible thread, and decidedly does not define at least one lateral stop rib.

The FOA provides no explanation of how Purdy teaches every element of claim 54. Claim 54 recites that a perimeter shape of the first flange differs that of the second flange. The flanges 204 of stent ring/rim 202 of Purdy (FIGS. 34-37) have identical perimeter shapes.

The FOA provides no explanation of how Purdy teaches every element of claim 55. Claim 55 recites that the first and second flanges forms differing, first and second patterns of radial indentations. The flanges 204 of the stent ring/rim 202 of Purdy do not form radial indentations, let alone differing patterns.

The FOA provides no explanation of how of Purdy teaches every element of claim 57. Claim 57 recites that the rim forms a plurality of recesses, and that each of the recesses are non-

symmetrical. The stent ring/rim 202 of Purdy does not form any recesses, let alone non-symmetrical recesses. To the extent the Examiner views the single, continuous annular gap between the flanges 204 of Purdy as being a "recess", this interpretation decidedly does not teach a plurality of non-symmetrical recesses.

The FOA provides no explanation of how Purdy teaches every element of claim 58. Claim 58 recites that the recesses are defined by a leading surface and a trailing surface, and further that an angle of extension of the surfaces relative to a lateral edge differs. The stent ring/rim 202 of Purdy does not form a plurality of recesses, let alone recess surfaces of different extension angles.

Independent Claim 51

The FOA and NFOA both rejected independent claim 51 as being anticipated by Purdy without any explanation of how the features of claim 51 are taught by Purdy. Claim 51 is directed toward a suture holder comprising a shaft and a translating member. Purdy does not disclose a suture holder having the shaft and translating member features of claim 51; Applicant is entitled to at least a cursory explanation of how Purdy is possibly being viewed as anticipating claim 51. In the absence of any explanation or examination, the rejections of independent claim 51, as well as claims 52 and 53 depending from claim 51, as being anticipated by Purdy should be withdrawn.

CONCLUSION

Any inquiry regarding this Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005.

Respectfully submitted,

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By their attorneys,

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